

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

**As rescanning documents *will not* correct images,
please do not report the images to the
Image Problem Mailbox.**

UK Patent Application

GB 2 255 019 A
(19) (11) (13)
(43) Date of A publication 28.10.1992

(21) Application No 9107080.5

(22) Date of filing 04.04.1991

(71) Applicant
Neil William Rasburn
31 Almond Brook Road, Standish,
Wigan, WN6 0TB, United Kingdom

(72) Inventors
Neil William Rasburn
John Knowles Stanley

(74) Agent and/or Address for Service
Withers & Rogers
4 Dyer's Buildings, Holborn,
London, EC1N 2JT, United Kingdom

(51) INT CL^s
A61F 5/34

(52) UK CL (Edition K)
ASR RBP

(56) Documents cited
GB 1319574 A EP 0001357 A1 WO 83/01192 A1
US 4573453 A US 4269177 A

(58) Field of search
UK CL (Edition K) ASR RBP RBQ RFB
INT CL^s A61F 5/01 5/04 5/30 5/32 5/34 13/10
Online databases: WPI

(54) Pressure sleeve for reduction of digital swelling

(57) Accidental or surgical trauma to the body, generally gives rise to swelling. Because finger joints are surrounded by tendon and ligament only and, therefore, lack the hydromechanical action of muscle to reduce the swelling of the joint, such joints are particularly prone to prolonged swelling which prevents correct flexion of the finger. By rolling a device comprising a hollow fluid-filled sleeve having a continuous and endless elastomeric wall (12) formed as two tubes (12A, 12B) one inside the other and connected together at respective ends, back and forth along the finger from tip to base, accumulated intracellular fluid is urged towards the lymphatics hence reducing the swelling. The device may be inflated using an inflation tube (18) with a self-sealing valve (20).

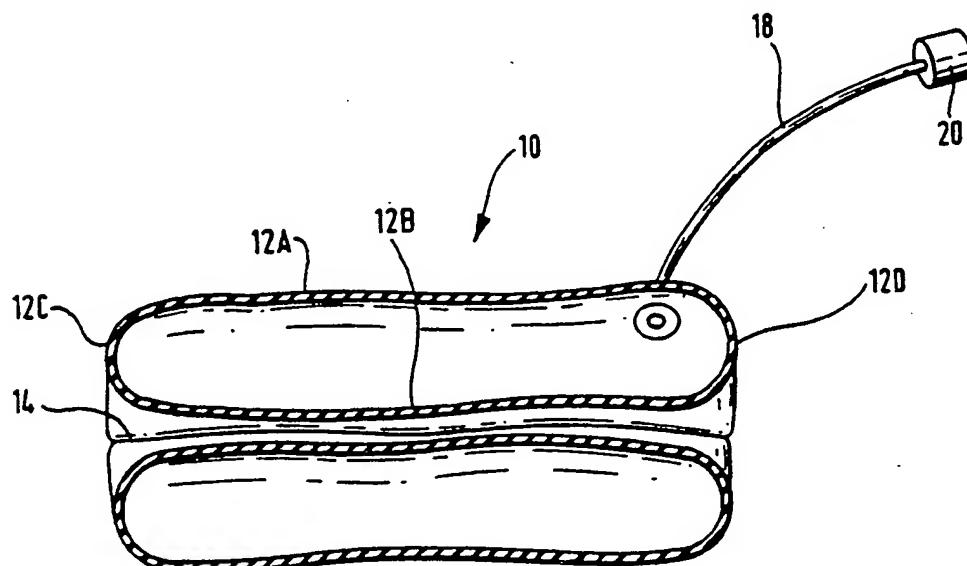


Fig. 2.

At least one drawing originally filed was informal and the print reproduced here is taken from a later filed formal copy.

The claims were filed later than the filing date within the period prescribed by Rule 25(1) of the Patents Rules 1990.

GB 2 255 019 A

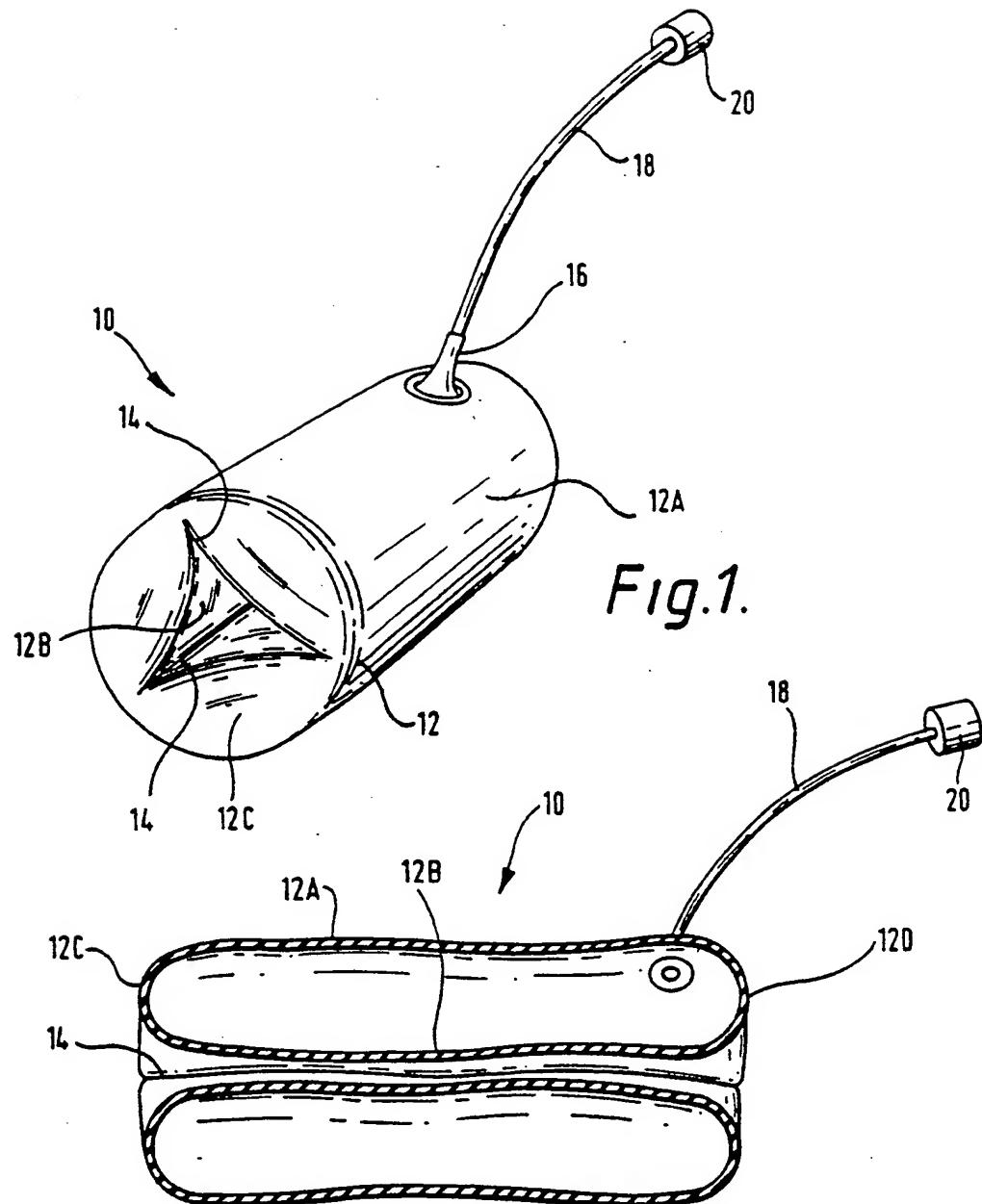


Fig. 2.

A DEVICE FOR THE REDUCTION OF DIGITAL OEDEMA

This invention relates to digital oedema therapy, and in particular to a device for such therapy.

5

Both accidental and surgical trauma to the hand gives rise to swelling, as it does in any other part of the body. The effect of this swelling is to reduce hand function, impede rehabilitation, and prolong the period of time the patient 10 spends away from useful activity. Injuries to the joints of the fingers are particularly prone to prolonged swelling, the effect of which is directly to prevent correct flexion of the finger. A finger tends to stay swollen for much longer than say a knee or an elbow because, in essence, the 15 fingers do not have any muscle within them or across any of the joints. Instead, the joints are surrounded by tendon and ligament only and, therefore, lack the hydromechanical action of muscle that is usually effective in reducing the swelling of the joint. As a result, a swollen finger joint 20 requires external pressure to be applied.

It is known to apply pressure to the finger for the reduction of oedema by massaging the finger, or by wrapping string around it. The latter technique involves taking a 25 piece of sash cord, for instance, and wrapping it around the finger tightly, starting at the tip of the finger and continuing until the base of the finger is reached, and then removing the string. This has the effect of reducing some of the swelling and allows improved flexion of the joint. 30 However, the technique is time consuming and uncomfortable for the patient, and is difficult if a middle or ring finger is involved. A further technique is to use an external pressurised box or giant glove which is pulse inflated to reduce the swelling of the hand and wrist. This is a

complex method of treatment and does not specifically treat the fingers where the main problem usually lies.

It is an object of the present invention to provide for 5 specific treatment of finger injuries and finger swelling causing restriction of flexion.

According to this invention, a device for the reduction of digital oedema comprises a hollow fluid-filled sleeve having 10 a continuous and endless elastomeric wall formed as two tubes one inside the other and connected together at respective ends. Typically, the length of the sleeve is in the region of 30mm to 50mm, with a diameter in the region of 20 to 35mm when in use. The sleeve is preferably inflated 15 with air or another gas or a liquid through a self-sealing valve and a tube connecting the valve to an opening in the wall of the sleeve. Since the continuous wall is endless, the inflated device may be progressively rolled onto the finger, with the wall material forming the inner tube 20 continuously rolling around the trailing end to form the outer tube and vice versa at the leading end. The device may be self-applied by the patient. The presence of an elastomeric outer wall allows a predetermined pressure to be applied largely irrespective of the size of the finger 25 without re-inflation or deflation.

While the length and diameter measurements given above are preferred, it is possible to construct a device of any length between 25mm and 60mm, and with an inflated outer 30 diameter of up to 40mm. The thickness of the elastomeric wall is preferably in the range of 0.3mm to 0.8mm, and preferably 0.5mm. The material typically has a shore hardness no greater than 50, and preferably in the region of 35 to 45.

By inflating the sleeve to a pressure in the region of, for example, 20 to 30mm of mercury and rolling the sleeve back and forth along the finger from tip to base, accumulated 5 intracellular fluid is urged towards the lymphatics and hence into a general circulation.

The invention will now be described by way of example with reference to the drawing in which:-

10

Figure 1 is a perspective view of a device in accordance with the invention, shown in an inflated condition; and

15

Figure 2 is a longitudinal cross-section of the device of Figure 1.

20

Referring to the drawings, a device for the reduction of digital oedema is in the form of an inflated or inflatable tube 10 having a thin continuous and endless elastomeric wall 12 so formed to constitute an outer tube 12A, which is generally cylindrical when the sleeve is inflated, and a coextensive inner tube 12B which is joined to the outer tube by end wall portions 12C and 12D. Since the actual length 25 of material of the inner wall in a transverse cross-section of the sleeve is substantially the same as the length of the material of the outer wall in the same cross-section, the inner wall forms a number of creases 14 as shown. The wall 12 is provided with an opening with a connection element 16 for connecting an inflation tube 18. This preferably 30 communicates with a releasable non-return valve 20 which is shown in the drawings at the distal end of the tube 18, but which could equally be located at the proximal end, forming part of the connection element 16.

In this preferred embodiment of the invention the length of the device when inflated is approximately 50mm and the outside diameter about 30mm. The device may be constructed from a rectangular sheet of medical grade latex rubber or 5 silicone rubber having a length of about 100mm and a width of about 60mm, although variations of these dimensions within the ranges 60mm to 120mm and 50mm to 70mm are possible. A double-walled hollow sleeve may be formed from the rectangular sheet by joining together the two longer 10 edges and then joining the two shorter edges together.

Before inflation, the inner diameter of the tube may be in the region of 20 to 25mm. When inflated the inner wall becomes creased as shown in the drawing, while the outer 15 wall stretches.

The sleeve 10 may be filled with a fluid such as air or another gas, or even with a silicone liquid through tube 18, preferably to a pressure in the region 20 to 30mm of 20 mercury. At this point, it is best to arrange the sleeve so that the inflation tube 18 is adjacent one end. Then, the end of the sleeve furthest from the inflation tube 18 is placed on the tip of the finger and the sleeve is rolled onto the finger with the material of the outer wall 12A 25 moving forwards and around the end 12C to form the inner wall 12B as the material of the inner wall 12B moves around the other end 12D to form the outer wall 12A. The air or liquid within the sleeve exerts a gentle compressive force. The sleeve is preferably rhythmically rolled down the finger 30 from tip to base. Since the circumference of the finger increases towards its base, pressure within the sleeve increases as the finger is progressively inserted, so that the finger is massaged and the accumulated intracellular serous fluid within it is mobilized towards the lymphatics

and hence into the general blood circulation. Repeated movement up and down the finger is preferably performed over a period of several minutes.

5 The pressure within the device is not critical, but 20 to 30mm of mercury is generally more than sufficient to overcome the natural tendency for fluid to collect within the finger since the normal osmotic pressure of the fluid amounts to some 7 to 8mm of mercury. Very high pressures 10 are generally unsuitable since they cause distention of the device and prevent its ease of use on the middle two fingers (a problem with some prior methods of treatment).

15 The pressure within the device can be increased or decreased via the inflation tube 18 and the valve 20. Use of a tube 18 is not essential to the invention, and a valve may be incorporated directly in the wall 12A, substantially flush-fitted.

20 A trial with an air-filled device has shown very high patient compliance with its use, and some particularly effective results, in that chronic finger swelling of the type that might occur for anything up to a year following a joint injury was dramatically reduced within minutes of 25 using the device. This improvement allowed greater flexion of the finger joint which, in turn, allowed for better natural reduction of the oedema. Although there was a relapse of the finger swelling, it was never to the same degree as that before treatment. A reduction in 30 circumference at the proximal interphalangeal joint amounting to 1mm in diameter improved the range of movement of the finger by 2.7° per millimetre of diameter reduction on average, and within a period of 3 to 4 weeks of using the device large improvements in finger flexion were noted.

Beyond 80° of flexion was achieved with the result that natural pressure generation within the finger by the fat pads of the finger on either side of the joint meeting was found to be sufficient to maintain the improvement.

CLAIMS

1. A device for the reduction of digital oedema comprising a hollow fluid-filled sleeve having a continuous and endless elastomeric wall formed as two tubes one inside the other and connected together at respective ends.
- 5
2. A device according to claim 1 having a self-sealing valve and a tube connecting the valve to an opening in the wall of the sleeve.
- 10
3. A device according to any preceding claim, wherein the sleeve is inflated with air or another gas, or a liquid.
- 15
4. A device according to claim 3, wherein the sleeve is inflated to a pressure in the range of 2666Pa to 3999Pa (20mm to 30mm of mercury).
- 20
5. A device according to any preceding claim, wherein the length of the sleeve is between 25mm and 60mm.
6. A device according to any preceding claim, wherein in use, the outer diameter of the device is up to 40mm.
- 25
7. A device according to any preceding claim, wherein the thickness of the elastomeric wall is in the range of from 0.3mm to 0.8mm.
- 30
8. A device according to any preceding claim, wherein the elastomeric wall has a shore hardness in the range of 35 to 45.
- 35
9. A method of reducing digital oedema whereby, a device comprising a hollow fluid-filled sleeve having a continuous and endless elastomeric wall formed as two tubes one inside the other and connected together at

respective ends is rolled onto a finger, the wall material forming the inner tube continuously rolling around the trailing end to form the outer tube and the outer tube continuously rolling around the leading end to form the inner tube.

5

10. A device for the reduction of digital oedema substantially as described herein, with reference to the drawing.

10

Patents Act 1977

Examiner's report to the Comptroller under
Section 17 (The Search Report)

Application number

9107080.5

Relevant Technical fields

(i) UK CI (Edition K) A5R RBP RBQ RFB

(ii) Int CL (Edition 5) A61F 5/01 5/04 5/30 5/32 5/34
13/10

Search Examiner

MISS E M COLEMAN

Databases (see over)

(i) UK Patent Office

(ii) ONLINE DATABASE: WPI

Date of Search

20 JULY 1992

Documents considered relevant following a search in respect of claims

1 TO 10

Category (see over)	Identity of document and relevant passages	Relevant to claim(s)
X	GB 1319574 A (MOBUL) particularly Figure 3 and page 1 lines 62-70	1, 3, 10
X	EP 0001357 A1 (RHYS-DAVIES) whole document	1, 3, 5, 9, 10
X	WO 83/01192 A1 (HBX VARIX) see Figures and Claim 1	1, 3, 9, 10
X	US 4573453 (TISSOT) whole document	1, 3, 10
X	US 4269177 (CLARK) whole document	1, 2, 9, 10

Category	Identity of document and relevant passages	Relevant to claim(s)

Categories of documents

X: Document indicating lack of novelty or of inventive step.

Y: Document indicating lack of inventive step if combined with one or more other documents of the same category.

A: Document indicating technological background and/or state of the art.

P: Document published on or after the declared priority date but before the filing date of the present application.

E: Patent document published on or after, but with priority date earlier than, the filing date of the present application.

&: Member of the same patent family, corresponding document.

Databases: The UK Patent Office database comprises classified collections of GB, EP, WO and US patent specifications as outlined periodically in the Official Journal (Patents). The on-line databases considered for search are also listed periodically in the Official Journal (Patents).

Relevant Technical fields

(i) UK CI (Edition K) A5R RBP RBQ RFB

Search Examiner

MISS E M COLEMAN

(ii) Int CL (Edition 5) A61F 5/01 5/04 5/30 5/32 5/34
13/10

Databases (see over)

(i) UK Patent Office

Date of Search

20 JULY 1992

(ii) ONLINE DATABASE: WPI

Documents considered relevant following a search in respect of claims

1 TO 10

Category (see over)	Identity of document and relevant passages	Relevant to claim(s)
X	GB 1319574 A (MOBUL) particularly Figure 3 and page 1 lines 62-70	1, 3, 10
X	EP 0001357 A1 (RHYS-DAVIES) whole document	1, 3, 5, 9, 10
X	WO 83/01192 A1 (HBX VARIX) see Figures and Claim 1	1, 3, 9, 10
X	US 4573453 (TISSOT) whole document	1, 3, 10
X	US 4269177 (CLARK) whole document	1, 2, 9, 10

THIS PAGE BLANK (USPTO)